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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,350	04/18/1997	ALASDAIR R. MACLEAN	117-231	1818

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/20/2002

81

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/776,350

Applicant(s)
MacClean et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 5, 2002/May 9, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-51 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed April 15, 2002 (Paper No. 30) and May 9, 2002 (Paper No. 31) are acknowledged and have been entered. Claim 43 has been amended and claims 52-58 have been canceled. An action on the RCE follows.

2. Claims 43-51 are pending and currently under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are maintained:

Maintained and New Claim Rejections - 35 USC § 112

5. Claims 46, 48-50 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 25, Section 5, pages 2-4 and further for the reasons set forth below.

Applicant argues that the subject matter of claim 43 does not relate to a whole universe of HSV-1 mutants but rather require a very specific class of mutants which are defined as having a non-functional gamma 34.5 gene in the long repeat region RL and that claim 46 is limited to a very specific mutation in the long repeat region of HSV-1 (claim 46) which examiner admits is recited in the specification. The arguments have been considered but have not been found persuasive as drawn to claims 46 and 48-50. Although the claimed invention is enabled for the invention of

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claim 43, the invention is not enabled for the inventions as limited in claims 46 and 48-50 because only two examples of avirulent HSV-1 for the treatment of cancers are known, that is the 1716 species of the instant application and the prior art 3616. Species 1716 contains a specific 759 bp deletion in the gamma 34.5 gene and 3616 contains a specific 1000 bp deletion in the gamma 34.5 gene. No other successful deletions are taught in the specification or in the art of record. No general principles that would guide the artisan in the making of the claimed deletions have been set forth so that the artisan is left to random experimentation in order to practice the claimed invention. Random experimentation is undue. In the absence of specific teachings in the claims for the sites at which deletions will function as claimed, it cannot be predicted whether or not deletions at unspecified and unlimited sites within the gamma 34.5 gene will lead to disabling the virus or would cause the virus to undergo recombination which could reinstate full neurovirulence and full viral activity. Further, as drawn to Claim 46, WO92/13943 specifically teaches that a number of variants of HSV type 1 (strain 17) with defined deletions in the unique and repeat sequences of the long and short regions of the viral genome have already been isolated (para bridging pages 2-3) and that it has been surprisingly found that HSV-1 Glasgow strain 17 variants modified in the terminal portion of RL lack neurovirulence (p. 3, lines 2-5) and that these variants, although incapable of replicating in CNS neurons were capable of replication in the peripheral tissue (p. 3, lines 6-11) and that the spontaneously occurring variant of 1702, 1714, lacks a 759 bp region and the virus is non-neurovirulent. Species 1716 is a wild-type Glasgow strain 17+ in which the 759 bp deletion in variant 1714 has been introduced (p. 4,

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lines 15-31). Thus, it is clear that not any mutant strain 17 virus will function as claimed and it would not be expected that strain 17 mutants with deletions in the short regions of the viral genome would function as claimed and the specification does not teach how, other than for the specifically taught deletions, to produce strain 17 mutants, that will function as claimed.. For the reasons set forth previously and above, one of skill in the art would be forced into undue experimentation to practice the claimed invention. Applicant's arguments have not been found persuasive and the rejection is maintained. The rejections can be obviated by canceling claims 46 and 48-50.

6. Claims 43-51 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 25, Section 8, page 7.

The rejection of the claims under 35 CFR 112, first paragraph is maintained because applicant did not distinctly and specifically point out the supposed errors in the rejection.

Claim Rejections - 35 USC § 103

7. Claims 43-51 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 25, Section 7, pages 6-7.

Applicant reiterates arguments drawn to the lack of enablement of US Patent No. 5,585,096 and states that the secondary references fail to cure the deficiencies of US patent No. 5,585,096. The arguments have been reconsidered but have not been found persuasive for the reasons previously set forth.

Applicant submits the Cruickshank Declaration which reiterates arguments drawn to the lack of enablement of US Patent No. 5,858,096 and states that the

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secondary references fail to cure the deficiencies of US Patent No. 5,585,096. The arguments have been reconsidered but have not been found persuasive for the reasons previously set forth. Further, Dr. Cruickshank states that "it seems to me that one of ordinary skill in the art would have appreciated that the inclusion of intracranial melanoma in the list of tumor cells provided in col 3, lines 49-58 is more of a catch-all list of what might be hoped-for rather than a reasoned claim that usefully had envisaged a specific, credible extracranial application. The argument has been considered but has not been found persuasive because as previously stated, issued US Patents are enabled. The invention was obvious for the reasons previously set forth and was clearly enabled, as demonstrated by the instant application. Dr. Cruickshank's stated opinion does not overcome the rejection of record. Dr. Cruickshank further argues that the wild-type virus has cell type and cell cycle specific activity which would imply that failure of replicative cytotoxicity might well occur in some cells and US Patent No. 5,585,096 did not use other cell types and the Dr. Cruickshank does not believe that the evidence provided in US Patent No. 5,585,096 would have persuaded an ordinarily skilled worker in this field that such virulent strains of HSV could be successfully used to treat tumors of a non-neuronal origin. The arguments have been considered but have not been found persuasive because Dr. Cruickshank's arguments appear to be drawn only to the cited US Patent without clearly addressing the combined teachings wherein it was known in the art that melanoma metastasizes to the brain and that HSV-1 infects metastatic melanoma and that HSV-1 mutant 1716 was known. It must be remembered that the references are relied upon in combination and are not meant to

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be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. Claims 46-51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-51 are indefinite in the recitation of "mutant virus". There is no antecedent basis for "mutant virus" in claim 43 from which the claims depend.

Claim 51 is indefinite in the recitation of the mutant virus strain 1716. The claim is indefinite in the use of the virus strain 1716 as the sole means of identifying the claimed virus. The use of laboratory designations only to identify a particular virus renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct constructs. Amendment of the claims to include the depository accession number of the virus is required, because deposit accession numbers are unique identifiers which unambiguously define a given virus.

New Grounds of Objection

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9. The amendment filed January 22, 2001 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is the incorporation by reference of the parent applications of the instant application. MPEP 201.06© specifically states that:

A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).

Applicant is required to cancel the new matter in the response to this Office action.

10. All other objections and rejections recited in Paper No. 25 are hereby withdrawn.

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

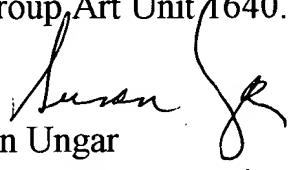
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(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.


Susan Ungar
Primary Patent Examiner
May 13, 2002